scope of claims in any way are done so without prejudice. In addition, the Specification has been amended to provide a cross-reference to the parent application of the present application. No new matter has been added by this Amendment.

Rejection under Obviousness-Type Double Patenting

Claims 4-6, 8 and 10-29 are rejected under the judicially created doctrine of double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 5,972,712. The Office Action states that although the conflicting claims are not identical, they are not patentably distinct from each other because both teach methods of evaluating the clotting characteristics of blood. A Terminal Disclaimer with respect to U.S. Patent No. 5,972,712 will be filed when patentable subject matter has been determined.

Rejection under 35 U.S.C. § 102(b)

Claims 4-6, 8 and 10-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Triplett *et al.* This rejection is respectfully traversed.

The CAFC has stated that anticipation requires the presence in a single prior art reference of the disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenefabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Altco Standard Corporation v. Tennessee Valley Authority*, 1 USPQ 1337, 1341 (Fed. Cir. 1986); 774 F.2d 1082 (Fed. Cir. 1985). Triplett *et al.* do not recite every element of claims 4-6, 8 and 10-29 and therefore do not anticipate claims 4-6, 8 and 10-29.

Independent claims 4, 8, and 26, which are directed towards methods of determining platelet functionality or the clotting characteristics of a blood sample, have been amended herein to clarify one of the distinguishing features of the methods of the instant invention, namely that the methods utilize a plunger sensor apparatus comprising at least one test cell and a plunger assembly within the test cell. The clotting test is performed on an aliquot of the blood sample contained in the cell by reciprocating the plunger within the cell. The recitation of the operation of the plunger in the body of Independent claims 4, 8, and 26 makes it clear that the plunger is integral to the method being claimed. Dependent claims 5-6, 10, 13-14, 16, 18-24, and 27-30, which depend from claims 4, 8, or 26, also contain by their dependency the distinguishing elements of claims 4, 8, and 26.

Triplett *et al.* teach a clotting test sensitive to Lupus Anticoagulant that involves mixing a plasma sample with a phospholipid suspension and a solution of phospholipid dependent prothrombin activator (PLDPA), followed by the addition of a sufficient amount of calcium chloride solution. Clotting is measured by photometric turbidity measurement (column 8, lines 15-22).

However, no where do Triplett *et al.* teach or even suggest a platelet functionality test or a clotting test wherein the test method utilizes a plunger sensor apparatus having a plunger assembly. Triplett *et al.* do not teach or suggest a method wherein the platelet functionality test or the clotting test is performed by reciprocating a plunger within the test sample.

Because Triplett *et al.* fail to teach each and every claimed element, Triplett *et al.* do not anticipate claims 4-6, 8 and 10-29. In addition, because Triplett *et al.* teach away from the elements of claims 4-6, 8 and 10-29, Triplett *et al.* also fail to make claims 4-6, 8 and 10-29 obvious. For at least these reasons, claims 4-6, 8 and 10-29 are not anticipated or made obvious by Triplett *et al.* Withdrawal of this Section 102(b) rejection is respectfully requested.

CONCLUSIONS

It is believed that all the claims now pending in this patent application, as amended and described above, are now allowable. Therefore, it is respectfully requested that the Examiner reconsider his rejections and to grant an early allowance. If any questions or issues remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number listed below. It is believed that no fees are required in filing this Amendment and Remarks. However, should any fee be required, please charge Deposit Account No. 50-1123.

Respectfully submitted,

October 29, 2001
Dated

Steven C. Petersen, Reg. No. 36,238
HOGAN & HARTSON, L.L.P.
1200 Seventeenth Street, Suite 1500
Denver, CO 80202
Telephone: (720) 406-5315
Facsimile: (720) 406-5301

VERSION WITH MARKING SHOWING CHANGES MADE TO SPECIFICATION

On page 1, below the title "TEST CARTRIDGE FOR EVALUATING BLOOD PLATELET FUNCTIONALITY," center and insert the heading --CROSS-REFERENCE TO OTHER APPLICATIONS--.

On page 1, before the heading "BACKGROUND OF THE INVENTION," please insert --This application is a divisional of U.S. Patent Application No. 08/640,275, filed April 30, 1996, now issued as U.S. Patent No. 5,925,319.--.

MARKED UP VERSION SHOWING CHANGES MADE TO CLAIMS

Please cancel claims 15, 17, 25, and 31.

4. (Twice amended) A method for determining platelet functionality of a blood sample using a plunger sensor apparatus comprising at least one test cell and a plunger assembly within said test cell, the method comprising:

(a) [dividing said sample into a plurality of aliquot samples] dispensing an aliquot of said sample into said test cell;

(b) adding a selected amount of a platelet activating reagent to [each of] said aliquot sample to form a reaction mixture [samples, the amount of said platelet activating reagent in each said aliquot sample differing from the amount of said platelet activating reagent in each other aliquot sample];

(c) adding a sufficient amount of a clotting reagent to [each] said [aliquot sample] reaction mixture to promote clotting of said aliquot sample;

(d) performing a clotting test on [each] said aliquot sample by alternately lifting the plunger assembly and allowing the plunger assembly to descend through the test mixture; and

(e) determining said platelet functionality of said sample based on the [difference in] clotting times for [each] said aliquot sample, wherein said clotting time[s are] is determined by measuring a change in viscosity of said aliquot sample [samples].

8. (Twice Amended) A method for determining clotting characteristics of a blood sample using a plunger sensor apparatus comprising at least one test cell and a plunger assembly within said test cell, said method comprising:

(a) [dividing said sample into a plurality of aliquot samples] dispensing an aliquot of said sample into said test cell;

(b) adding a selected amount of a platelet activating reagent to [each of] said aliquot sample to form a reaction mixture [samples, the amount of said platelet activating reagent in each said aliquot sample differing from the amount of said platelet activating reagent in each other aliquot sample];

(c) adding a sufficient amount of a clotting reagent to [each] said [aliquot sample] reaction mixture to promote clotting of said sample;

(d) performing a clotting test on [each] said aliquot sample by alternately lifting the plunger assembly and allowing the plunger assembly to descend through the test mixture; and

(e) determining clotting characteristics of said sample based on the [difference in] clotting times for [each] said aliquot sample.

13. (Amended) The method of claim 4, wherein the amount of said platelet activating agent in [each] said aliquot sample is between about 0 and about 2.76 micrograms.

14. (Amended) The method of claim 4, wherein the concentration of said platelet activating reagent in [each] said aliquot sample is between about 0 and about 150 nM.

20. (Amended) The method of claim [10] 26, wherein the amount of said platelet activating agent in each said aliquot sample is between about 0 and about 2.76 micrograms.

21. (Amended) The method of claim [10] 26, wherein the concentration of said platelet activating reagent in each said aliquot sample is between about 0 and about 150 nM.

22. (Amended) The method of claim [8] 26, wherein at least one of said aliquot samples contains no platelet activating reagent, and wherein each remaining aliquot sample comprises different amounts of said platelet activating reagent.

24. (Amended) The method of claim 8, wherein said clotting [times are] time is determined by measuring a change in viscosity [of each] of said aliquot sample [samples].

26. (Amended) A method for performing an activated clotting time test on a sample of blood using a plunger assembly apparatus comprising a multicell test cartridge, said cartridge comprising at least a first, a second and a third test cell and a plunger assembly within each of said test cells, each of said cells comprising a sufficient amount of a contact activator to achieve clotting, wherein said first cell further comprises a first amount of a platelet activating reagent and wherein said second cell comprises a second amount of said platelet activating reagent, said first and second amounts being different, said method comprising:

(a) dividing said sample into first, second and third partial samples;

(b) dispensing the first partial sample into the first test cell to form a first test mixture;

(c) performing a first activated clotting time test on the first test mixture by reciprocating said plunger assembly within said first cell to obtain a first clotting time;

(d) repeating the aforementioned steps of dispensing and performing an activated clotting time test on each of said second and third partial samples to obtain a second and third clotting time; and

(e) comparing the clotting time of said first, second, and third partial samples to determine the activated clotting time of the sample of blood based on the clotting time times of said first, second and third partial samples.